HIPAA Overview
CREST
May 14, 2015

Waiver of Authorization

- Similar to a waiver of consent
- If certain criteria are met, permits a covered entity to use or disclose protected health information for research without an authorization
- Waiver of authorization can be approved by either:
  - Institutional Review Board
  - Privacy Board
HIPAA Change: Waiver of Authorization

- Change
  - Dissolution of MSU Privacy Board
  - MSU IRBs will review WOA requests
    - Expedited Review – Retrospective Research
    - Convened Review – Prospective Research

- Rationale
  - IRB will already be familiar with the project as it is being reviewed and can consider request in conjunction with any requests for waiver of consent
  - Eliminate the need for a duplicate review by another committee
  - In line with the practice of many other IRBs that review requests for waivers of authorization

Highlights of the changes are:

- Use of Protected Health Information Application for projects involving PHI.
- The IRB will review waiver of authorization requests instead of a separate Privacy Board when MSU is the covered entity or when an arrangement has been made with another entity to conduct such reviews.
- The HRPP will implement use of a Research Authorization Form if the Protected Health Information (PHI) for research will be obtained from a clinic that is part of the MSU covered entity.
- If PHI from an MSU Health Team clinic may be accessed for research, the HRPP will notify the MSU Health Team Compliance office to facilitate communication between the researcher and the covered entity.
- Removal of HRPP Manual Section 5-7, Privacy Board and 6-6-B, Health Insurance Portability and Accountability Act.
New HRPP Manual Sections

7-6, Health Insurance Portability and Accountability Act Compliance in Human Research

- Describes the HIPAA requirements as they relate to human research
- Describes the role of the Human Research Liaison (HRL) in the review of projects that involve PHI

7-6-A, Individual Authorization

- Requirement to use the MSU Health Team Research Authorization for a clinic that is part of the MSU covered entity
- HRL review of individual authorization forms
- If PHI will be obtained from MSU, HRL provides notice to the MSU Health Team
- Requirements for authorizations

New HRPP Manual Sections

7-6-B, Alteration or Waiver of Individual Authorization

- MSU IRB review of requests for an alteration to, or waiver, in whole or in part, of the individual authorization for use or disclosure of PHI obtained from a clinic that is part of the MSU covered entity
- MSU IRB may review requests where PHI will be obtained from a non-MSU covered entity if the MSU IRB has entered into an arrangement with the non-MSU covered entity to review such requests
- Review and documentation requirements for alteration or waiver of individual authorizations
New HRPP Manual Sections

7-6-C, Review Preparatory to Research
- Describes the HIPAA requirements for reviews preparatory to research and its relationship to IRB review, including contacting prospective subjects

7-6-D, De-Identification
- Describes the HIPAA requirements for de-identification
- HRL will provide notification to the MSU Health Team and copy the PI if the request involves a clinic that is part of the MSU covered entity.

Summary of the Changes
- Use of PHI for research: submit a separate application.
- If MSU HT is the covered entity (CE) use the new authorization template.
- If MSU is the CE the MSU Privacy Officer (PO) is made aware of the use of PHI for research.
- IRB will review requests for waivers of authorizations.
- Multisite research will require each CE to review the use of PHI at their institutions.
Questions?